REMARKS

In view of the foregoing amendments and the following representations, reconsideration and allowance of the above-identified application is respectfully requested.

All the claims as originally filed, claims 1-11, have been canceled without prejudice. New claims 12-30 are submitted for consideration and are in the present application. No new matter is added by the newly presented claims. Support can be found in claims 1-11 as originally filed and in the specification on page 3, lines 26-29, page 4, lines 8-11 and 29-34, page 5, lines 12-14, 25-27, page 6, line 32 to page 7, line 25 and Example 6 found on pages 13-17.

In the Office Action on page 2, second paragraph, the Examiner objected to the application because it did not contain an abstract on a separate sheet as required by 37 CFR § 1.72(b). In response to this objection, Applicants, submit herewith a new abstract on a separate sheet of paper.

In the Office Action on page 2, fourth paragraph, the Examiner rejected claims 2-5, 8 and 10 under 35 U.S.C. § 112, second paragraph. Applicants respectfully submit that this rejection is moot in view of the cancellation of these claims.

In the Office Action on page 3, fifth paragraph, the Examiner rejected claims 1-9 under the judicially created doctrine of obviousness-type double patenting in view of United States Patent No. 6,174,548. Applicants respectfully submit that this rejection is moot in view of the cancellation of claims 1-9 and the fact that the new claims are limited to pellet formulations.

In the Office Action on page 4, fourth full paragraph, the Examiner rejected claims 1-11 under 35 U.S.C. § 102(a/e) as being anticipated by Chen et al., United States Patent No. 6,174,548.

In the Office Action on page 5, third paragraph, the Examiner rejected claims 1-11 under 35 U.S.C. § 103(a) over Chen et al., United States Patent No. 6,174,548.

In response to these two rejections based upon Chen et al., Applicants respectfully submit that the rejections are not proper because the Chen et al. reference does not qualify as prior art to the present application. More specifically, the Chen et al. patent is the parent application of the present continuation-in-part application. On August 28, 1998, the application that resulted in the Chen et al. patent was filed with the United States Patent and Trademark Office and it was assigned Application No. 09/143,167. On August 27, 1999, the present continuation-in-part application was filed with the United States Receiving Office of the PCT and listed the United States as a designated states. The August 27, 1999 PCT application claimed priority to Application No. 09/143,167 (the Chen et al. patent). Thus, the present application is a continuation-in-part application filed within one year of the parent application (the Chen et al. application) and before publication of the Chen et al. application. Accordingly, the Chen et al. patent is not prior art and cannot be used as a basis to reject the present claims. In addition, the Chen et al. patent and the current application list the same inventors and both are assigned to the same entity, Andrx Pharmaceuticals, Inc.

In the Office Action on page 5, fifth paragraph, the Examiner rejected claims 1-7 and 9-11 under 35 U.S.C. § 103(a) as being unpatentable over Odidi et al, United States

Patent No. 6,296,876 in view of Kim, KR 9208161B (abstract only).

Applicants respectfully traverse this rejection.

The invention as recited in the newly submitted claims is a stable pellet that employs a core of omeprazole or a pharmaceutically acceptable salt of omeprazole and about 10 weight percent or less of lysine or arginine. This core is then directly enteric coated with a layer that comprises 5 to 50 weight percent of an inert processing aid. This formulation is surprising because it allows the use of low amount of an alkaline material while maintaining the required stability of omeprazole without the presence of a separately applied separating layer or subcoat between the core and the enteric coat.

At the time the applicants discovered the present invention it was well known that omeprazole was an acid sensitive drug and therefore its contact with acid sensitive materials such as enteric polymers should be avoid. See Col. 1 of U.S. Patent No. 4,786,505 and Col. 1 of the Odidi reference. It was also known that increasing the amount of alkaline material in the core could provide the necessary alkaline enviroment to stabilize omeprazole from the acid groups of the enteric polymer but the increase of alkaline material in the core could have adverse effects on the enteric, i.e cause it to degrade from the inside out. See United States Patent No. 4,786, 505, Col. 1, line 48 to Col. 2, line 4.

The solution to this dual problem of providing omeprazole with the necessary alkaline environment and preventing degradation of the enteric coating was to insert a separating layer or subcoating between the omeprazole core and the enteric coating. This solution involved an additional processing step that was undesired and time consuming.

In an effort to eliminate the need for a separate processing step to apply a separating layer between the enteric coat and the core, Applicants discovered the presently claimed invention, an omeprazole core that employs about 10 percent or less of a alkaline material selected from arginine or lysine and an enteric coat that employs 5-50 percent of an inert processing aid.

This unique combination of a low amount of alkaline material in the core and high amount of inert material in the coating, is not disclosed or suggested in any of the cited references.

The Odidi reference discloses omeprazole compositions that apply a separating layer between the omeprazole core and the enteric coating. See Col. 2, lines 40-50 and Example 1-6. Thus the Odidi reference teaches away from the presently claimed invention because it teaches the additional step of inserting a separating layer between the core and the enteric coat which is expressly disclaimed by the present claims.

The addition of the Kim abstract to the Odidi reference does not lead an individual of ordinary skill in the art to arrive at the presently claimed invention. The Kim abstract merely suggests preparing a core of omeprazole using arginine, lysine or histidine then applying a coating of a water soluble polymer prior to application of the enteric coating. Like Odidi, and numerous other prior art references, the Kim abstract merely teaches a stable omeprazole formulation with a separately applied separating layer or subcoat between the core and the enteric coating.

Applicants respectfully submit that none of the cited references disclose the unique pellet formulation recited in the newly present claims which is an core with about

10 weight percent or less of arginine or lysine that is directly enteric coated with a enteric coating material which contains 5-50 weight percent of an inert processing aid.

Applicants note that Lovgren, United States Patent No. 4,786,505, Kim, United States Patent No. 5,219,870, Klokkers et al., United States Patent No. 6,248,758, and Depui et al., United States Patent No. 6,365,184 were made of record.

Applicants wish to inform the Examiner, that submitted concurrently with this Amendment, Applicants are providing an Information Disclosure Statement which lists all the references cited in the parent application plus additional references that have come to Applicants attention based upon their involvement in a patent infringement litigation involving Lovgren United States Patent No. 4,786,505. The decision in that litigation is reported at *In re Omeprazole Litigation*, 222 F.Supp.2d 423 (S.D.N.Y. 2002). This decision is currently on appeal to the Court of Appeals for the Federal Circuit. Due to the large number of references cited in the Information Disclosure Statement, Applicants specifically would like to direct the Examiner's attention to references FA to FE. Although all the references identified in the Information Disclosure Statement are relevant, references FA to FE may be of particular relevance because they all relate to omeprazole formulations that directly apply an enteric coating onto an omerazole core. It is respectfully submitted that the newly present claims are patentable over these references because some of the references are not prior art such as United States Patent No. 6,096,340 and more importantly, none of the references dislcose a core containing about 10 weight percent or less of arginine or lysine that is directly enteric coated with an enteric coat containing 5-50 weight percent of an inert processing aid.

Based upon the foregoing amendments and representations, Applicants respectfully submit that the rejection of the claims in the above-identified application have been overcome and should be withdrawn. Early and favorable action is earnestly solicited.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on 3/24/03

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